DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3228n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

via Federal Express

November 29, 1999

MQSA Facility ID: 221019
Inspection ID: 2210190002
FDA Reference #: 2954142

Glorian Martinelli
Director of Imaging
Sutter Roseville Medical Center
Imaging Department
One Medical Plaza
Roseville, California 95661

Dear Ms. Martinelli:

We are writing to you because on September 15, 1999, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious problems involving the mammography procedures performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat level 2 and new level 2 findings at your facility, which represent departures from Title 21, Code of Federal Regulations (CFR), Part 900.

Level 2 Repeat: The interpreting physician, [redacted], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a twenty-four month period. {21CFR§900.12(a)(1)(ii)(A)}

Level 2 Repeat: The radiologic technologist, [redacted], did not meet the continuing education requirement of having completed a minimum of fifteen Continuing Education Units (CEUs) in a thirty-six month period. {21CFR§900.12(a)(2)(iii)}

Level 2: There is no written procedure for handling consumer complaints. {21CFR§900.12(h)}

Level 2: There is no written procedure for infection control. {21CFR§900.12(e)(13)}

Level 2: Four of five random reports reviewed did not contain an assessment category. {21CFR§900.12(c)(1)(iv)}

Additionally, the inspection revealed the following level 3 findings at your facility:

Level 3: The medical physicist's survey for x-ray unit 3, [redacted], located in Room 1, is incomplete because the decompression test was not performed. {21CFR§900.12(e)(5)(xi)}

Level 3: The chest wall edge of the compression paddle is visible on the test image for unit 1, [redacted] located in room Mammo. {21CFR§900.12(b)(8)(ii)(E)}

Level 3: The required personnel qualification documents were unavailable during the inspection. {21CFR§900.12(a)}

The specific problems noted above appeared on your initial MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. The first two findings listed in this letter are identified as repeat level 2 because they identify a failure to meet a significant MQSA requirement and indicate failure by your facility to implement permanent correction of problems found during your previous inspection.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represent serious violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Dawna M. Watson for
Patricia C. Ziobro
Director
San Francisco District

cc:
Bonnie Bessemer, MQSA Inspection Program Monitor
Mindy Malone, MQSA Inspector (2184)
Pamela A. Wilcox-Buchalla, R.N., M.B.A.